TOSOH MEDICS, INC.

TOSOH

DEC 17 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023091

Submitter:

Tosoh Medics, Inc.
347 Oyster Point Blvd., Suite 201
South San Francisco, CA 94080
Phone: (800) 248-6764
Fax: (610) 615-4970

Contact Person:

Lois Nakayama
Manager, Quality Assurance

Date of Summary Preparation:

September 16, 2002

Device Name:

ST AIA-PACK Testosterone

Classification Name:

Testosterone test system

Predicate Device:

Coat-A-Count Total Testosterone
Diagnostic Products Corporation
Los Angeles, CA U.S.A.
K831342

Device Description:

The ST AIA-PACK Testosterone is a competitive immunoenzymometric assay which is performed entirely in the AIA-PACK. Testosterone present in the test sample competes with enzyme-labeled testosterone for a limited number of binding sites on a testosterone-specific monoclonal antibody, immobilized on a magnetic solid phase. The magnetic beads are washed to remove unbound enzyme-labeled testosterone and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled testosterone that binds to the beads is inversely proportional to the testosterone concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

0050

Statement of Intended Use:

ST AIA-PACK Testosterone is designed for in vitro diagnostic use only for the quantitative measurement of Testosterone (LH) in human serum on specific TOSOH AIA System analyzers.

Substantial Equivalence:

Comparison Data:

The ST AIA-PACK Testosterone Assay is substantially equivalent to the previously cleared Diagnostic Product Corporation (DPC) Coat·A·Count Total Testosterone assay since both assays are equivalent in the analyte that is detected, their intended uses, and performance characteristics.

See Table 1 for a comparison of the salient characteristics of the ST AIA-PACK Testosterone to the currently marketed DPC Coat A Count Total Testosterone reagents.

Table 1
Comparison of Characteristics:
ST AIA-PACK Testosterone vs. DPC Coat A Count

	ST AIA-PACK Testosterone	DPC Coat·A·Count
Intended Use	Quantitative analysis of testosterone in serum	Quantitative analysis of testosterone in serum, plasma and extracted urine
Methodology	Enzyme Immunoassay	Radioimmunoassay
Assay Sample	Human serum	Human serum, plasma or urine
Analyte Detected	Total Testosterone	Total Testosterone
Antibody	Monoclonal (mouse)	Polyclonal
Assay Range	10 – 2200 ng/dL	4 – 1600 ng/dL
Reagent Form	Antibody-coated magnetic beads	Antibody coated polypropylene tubes
Antibody label	Alkaline Phosphatase	^{125}Iodine

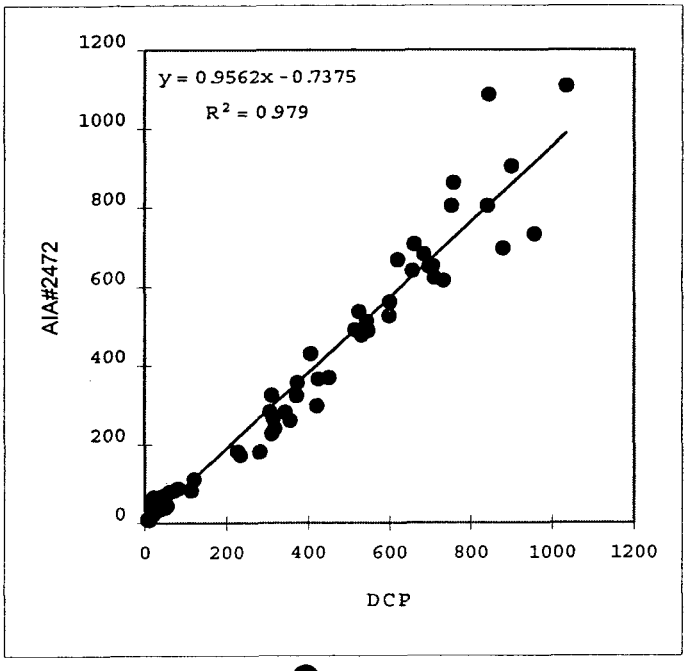
Comparative Analysis

Comparative analysis studies were performed with 71 serum samples by assaying the samples with the ST AIA-PACK Testosterone (y) and the DPC COAT-A-COUNT Total Testosterone Cat. No. TKTT1 (x) assays. A summary of the comparative analysis statistics is presented in Table 2 and a graphical representation of the data is shown in Figure 1.

Table 2
Comparative Analysis:
ST AIA-PACK Testosterone vs. DPC Coat A Count

Slope:	0.9562
Intercept:	-0.7375
Correlation Coefficient:	0.979
Range of Samples:	0.0 – 1107 ng/dL
Number of Samples:	71

Figure 1
Comparative Analysis
ST AIA-PACK Testosterone vs. DPC Coat A Count



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Precision studies demonstrated intra-run precision %CVs of 5.3% or less and inter-run precision %CVs of 5.99 or less. Recovery studies performed on spiked and diluted samples generated recoveries of 85.5% to 113.4% and 91.5% to 113.5%, respectively.

Conclusion:

Considering the excellent correlation between the Tosoh ST AIA-PACK Testosterone Enzyme Immunoassay and the DPC Coat A Count Total Testosterone assay, it can be concluded that the ST AIA-PACK Testosterone is substantially equivalent to the Coat A Count assay, which has been 510(k) cleared. Based on the establishment of substantial equivalence, the safety and effectiveness of the ST Tosoh AIA-PACK Testosterone assay is confirmed.

TOSOH MEDICS, INC.
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PREMARKET NOTIFICATION

INDICATION FOR USE STATEMENT

ST AIA-PACK Testosterone Assay

ST AIA-PACK Testosterone is intended for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of testosterone in human serum on specific TOSOH AIA System analyzers. Measurement of testosterone is used to aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

This device is intended "For Professional Use" only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K023091

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-CounterUse _____

(Optional Format 1-2-96)

347 Oyster Point Blvd., Suite 201, South San Francisco, California 94080 Tel: 650/615-4970 Toll Free: 1-800/248-6764 Fax: 650/615-0415

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2002

Ms. Lois Nakayama
Manager, Quality Assurance
Tosoh Medics, Inc.
347 Oyster Point Blvd, Suite 201
South San Francisco, CA 94080

Re: k023091
Trade/Device Name: ST AIA PACK Testosterone Assay
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class II
Product Code: CDZ
Dated: December 4, 2002
Received: December 5, 2002

Dear Ms. Nakayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K023091

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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